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09/883,642	06/18/2001	Denisa D. Wagner	CFBF-P02-004	3076

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/883,641	Applicant(s) WAGNER
	Examiner GAMBEL	Art Unit 1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on ____.

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) ____ is/are pending in the application. 39-88

4a) Of the above claim(s) ____ is/are withdrawn from consideration. 53, 54, 58, 59, 69-70, 75, 83, 87

5)☐ Claim(s) ____ is/are allowed.

6)☑ Claim(s) ____ is/are rejected. 39-52, 57, 60-68, 71-74, 76-82, 84-86, 88

7)☐ Claim(s) ____ is/are objected to.

8)☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on 4/30/01 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on ____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. ____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☑ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
4)☐ Interview Summary (PTO-413) Paper No(s). ____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

PAPER NO. 11

DETAILED ACTION

1. Applicant's election with traverse of Group XIII, methods of treating atherosclerosis with anti-P-selectin antibodies, in Paper No. 9, filed 11/13/02, 2 is acknowledged. The traversal is on the ground(s) that the segregation of Groups is an artificial construction and it would require no separate searching. This is not found persuasive because of the reasons of record. As pointed out in the previous Office Action (Paper No. 7). The restriction claims are drawn to patentably distinct methods relying upon patentably distinct products. The methods rely upon P-selectin ligands such as sialyl Lewis x, sialyl Lewis a, P-selectin, PSGL-1, 160 kD monospecific P-selectin ligand, P-selectin, or P-selectin mimic or antibodies thereto which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. In contrast to applicant's reliance on Class, subclass alone, the claimed methods employ various agents which are distinct because their structures and modes of action are different, which require non-coextensive searches. These agents are different with respect to biochemical properties; including primary, secondary and tertiary structure. Further, the antibodies binds targets which differ with respect to biochemical properties; including primary, secondary and tertiary structure as well as modes of actions. These molecules do not share a substantial structural feature essential to a common utility. Therefore, they are patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 39-88 are pending.

Claims 39-52, 57, 60-68 71-74, 76-82, 84-85, 86 and 88 drawn to methods of treating atherosclerosis wherein the agent is P-selectin-specific antibody are being acted upon as the elected invention.

Upon a review of the recitation of claim 87, claim 87 has been withdrawn from Group XIII, given that the recited agent is a mimetic of an inhibitor carbohydrate of P-selectin or PSGL, which is not a P-selectin-specific antibody.

Also, it is noted that the claims appear to be replete of inherent properties of methods of treating atherosclerosis with an anti-P-selectin antibodies. For examination purposes, many of the claimed limitations with respect to the nature of the cells or ligands or interactions will be examined as inherent or intrinsic properties of treating atherosclerosis with anti-P-selectin antibodies. If it is applicant's intention that the such limitations are not met by treating atherosclerosis with anti-P-selectin antibodies, then applicant should bring this attention to the examiner in the response to this Office Action. Such limitations and their respective claims would be subject to further restriction and/or species election and may be withdrawn from consideration in the instant application.

Applicant is invited to amend or provide claims that read on the elected invention of treating atherosclerosis with anti-P-selectin antibodies for clarity and to avoid confusion.

Claims 39-88, as they read on Groups I-XII and XIV-XXXII are withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Claims 1-38 have been canceled previously

For examination purposes, it is noted that it has been known in the art that PADGEM, GMP-140 and P-selectin are all the same molecule, that is, CD62P.

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2. Formal drawings, filed 11/13/02 (Paper No. 10), comply with 37 CFR 1.84.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

6. Claim 65 is objected to because "restinosis" should be "restenosis".

7. Claims 62-64 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 62-64 are indefinite in the recitation of "at least partially" "inhibit" or "reverse" because these "phrases" are relative in nature which renders the claims indefinite. The "phrases" which recite "at least partially" are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 39, 42-52, 57, 60-65, 68, 74, 76-82, and 88 are rejected under 35 U.S.C. § 102(b) as being anticipated by Furie et al. (EP 0496832) (1449; #AQ) (see entire document). Furie et al. teach methods of treating PADGEM-mediated events, including those associated with platelets, leukocytes and endothelial cells, in various processes, including atherosclerosis, clotting and inflammation, including the use of anti-PADGEM antibodies (e.g., see entire document, including the Description on columns 1-2 and Claims).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claims 60-61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be inherent properties of the referenced methods of treating atherosclerosis with anti-PADGEM antibodies. It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Also, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

11. Claims 39-52, 57, 60-68 71-74, 76, 80-82, 84, 86 and 88 are rejected under 35 U.S.C. § 102(b) as being anticipated by Palabrica et al. (WO 93/06863) (1449; #AU) (see entire document). Palabrica et al. teach methods of treating PADGEM-mediated events, including those involved with platelet deposition associated with inhibiting vascular narrowing in a number of cardiovascular procedures, including those associated with atherosclerosis, occlusive heart disease, restenosis, including the use of anti-PADGEM antibodies (e.g., see entire document, including the Background of the Invention, Detailed Description and Claims).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claims 60-61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be inherent properties of the referenced methods of inhibiting vascular narrowing in a number of cardiovascular procedures, including those associated with atherosclerosis with anti-PADGEM antibodies. Palabrica et al. teach known dosages and modes of administration, including prior to, during and following cardiovascular surgery, as well as factors routinely considered by the attending physician (see pages 13-14, overlapping paragraph to page 14, paragraph 2). It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Also, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

12. Claims 39-52, 57, 60-65,68, 73-74, 80-82, 85, 86 and 88 are rejected under 35 U.S.C. § 102 (a)(e) as being anticipated by McEver et al. (U.S. Patent No. 5,378,464) (see entire document). McEver et al. teach methods of inhibiting inflammatory responses, including those associated with ischemia and reperfusion, coagulation and atherosclerosis with effective amounts anti-GMP-140 antibodies that inhibiting GMP-140-mediated binding and adhesion and subsequent tissue damage(see entire document, particularly Diagnosis and Treatment of Disorders of the Inflammatory Response System on columns 20-23). McEver et al. acknowledge the well known use of thrombolytic agents at the time the invention was made (see column 20, paragraph 5).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claims 60-61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be inherent properties of the referenced methods of inhibiting atherosclerosis with anti-GMP-140 antibodies. It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. Also, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

13. Claims 39-52, 57, 60-68, 71-74, 76-82, 84-85, 86 and 88 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Furie et al. (EP 0496832) (1449; #AQ) AND/OR Palabrica et al. (WO 93/06863) (1449; #AU) AND/OR McEver et al. (U.S. Patent No. 5,378,464) in view of the art known use of combination therapies in the treatment of atherosclerosis, as taught by Coller et al. (U.S. Patent No. 5,976,532) (1449; #AO) in view of the art known underlying lesions of atherosclerosis and known treatments of atherosclerosis as acknowledged in the Background of the Invention on pages 1-2 of the instant specification and in view of the art known modes of administration practiced by the ordinary artisan at the time the invention was made, as acknowledged on pages 12-16 of the instant specification.

Furie et al. teach methods of treating PADGEM-mediated events, including those associated with platelets, leukocytes and endothelial cells, in various processes, including atherosclerosis, clotting and inflammation, including the use of anti-PADGEM antibodies (e.g., see entire document, including the Description on columns 1-2 and Claims). The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claims 60-61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be intrinsic or expected properties of the referenced methods of treating atherosclerosis with anti-PADGEM antibodies.

Palabrica et al. teach methods of treating PADGEM-mediated events, including those involved with platelet deposition associated with inhibiting vascular narrowing in a number of cardiovascular procedures, including those associated with atherosclerosis, occlusive heart disease, restenosis, including the use of anti-PADGEM antibodies (e.g., see entire document, including the Background of the Invention, Detailed Description and Claims). The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claims 60-61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be intrinsic or expected properties of the referenced methods of inhibiting vascular narrowing in a number of cardiovascular procedures, including those associated with atherosclerosis with anti-PADGEM antibodies. Palabrica et al. teach known dosages and modes of administration, including prior to, during and following cardiovascular surgery, as well as factors routinely considered by the attending physician (see pages 13-14, overlapping paragraph to page 14, paragraph 2).

McEver et al. teach methods of inhibiting inflammatory responses, including those associated with ischemia and reperfusion, coagulation and atherosclerosis with effective amounts anti-GMP-140 antibodies that inhibiting GMP-140-mediated binding and adhesion and subsequent tissue damage(see entire document, particularly Diagnosis and Treatment of Disorders of the Inflammatory Response System on columns 20-23). McEver et al. acknowledge the well known use of thrombolytic agents at the time the invention was made (see column 20, paragraph 5). The claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claims 60-61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be intrinsic or expected properties of the referenced methods of inhibiting atherosclerosis with anti-GMP-140 antibodies.

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosures of Furie et al., Palabrica et al. And McEver et al.

Furie et al., Palabrica et al. And McEver et al. each differ from the claimed methods in differences in their explicit teaching of all of the underlying cells and ligands associated with P-selectin-mediated binding, adhesion and activation. Given the combined teachings of P-selectin-mediated events, the claimed limitations encompassing cell types, ligands(e.g. see claims 42-52), the inhibitory properties of the claimed agent (e.g. see claims 60-61), the effects on atherosclerotic lesions (e.g. see claim 62-65) would be intrinsic or expected properties of the referenced methods of inhibiting atherosclerosis with anti-PADGEM or anti-GMP-140 antibodies. Furthermore, the combined teachings of Furie et al., Palabrica et al. and McEver et al. Provide for the various cell types and interactions associated with P-selectin mediated events.

Furie et al., Palabrica et al. and McEver et al. differ from the claimed methods in differences in their explicit teaching of the known underlying lesions in atherosclerosis and in the known use of cardiovascular interventions and surgery to treat atherosclerosis at the time the invention was made. The Background of the Invention acknowledges the art known underlying lesions of atherosclerosis and known treatments of atherosclerosis at the time the invention was made. In addition to the teachings of Furie et al., Palabrica et al. and McEver et al. to treat atherosclerosis with anti-GMP-140 / anti-PADGEM antibodies, Palabrica et al. teach the use of such antibodies to inhibit vascular narrowing in the context of the known cardiovascular procedures associated with the treatment of atherosclerosis at the time the invention was made.

Furie et al., Palabrica et al. and McEver et al. differ from the claimed methods in differences in their explicit teaching of all of the known modes and dosages of administration of therapeutics at the time the invention was made. Pages 12-16 of the instant specification acknowledges that the art known modes of administration practiced by the ordinary artisan at the time the invention was made in order to meet the needs of the patients and conditions being treated. In addition to the teachings of Furie et al., Palabrica et al. and McEver et al. of treating atherosclerosis with effective amounts of anti-PADGEM / anti-GMP-140 antibodies, Palabrica et al. also teach known dosages and modes of administration, including prior to, during and following cardiovascular surgery, as well as factors routinely considered by the attending physician (see pages 13-14, overlapping paragraph to page 14, paragraph 2).

In addition to the teachings of Palabrica et al. And the acknowledgment in the Background of the Invention in the instant application, Coller et al. teach the art known vessel-corrective techniques at the time the invention was made in the treatment of cardiovascular disorders such as atherosclerosis and restenosis, including angioplasty, atherectomy and coronary bypass surgery (see Background of the Invention on column 1 and Utility of Platelet-specific Chimeric Immunoglobulin on columns 5-7). In teaching the use of an inhibitor of platelet aggregation and thrombus formation associated with such conditions, Coller et al. teach the art known use of combination therapy with other drugs such as thrombolytic agents and that the amounts administered before, along with or subsequent to treatment will depend on a variety of factors and clinical symptoms known to the ordinary artisan at the time the invention was made (see column 6, paragraphs 2-3).

Given the art known practice of combination therapy, as taught by Furie et al., Palabrica et al., McEver et al., in view of the art known use of combination therapies in the treatment of atherosclerosis, as taught by Coller et al. and in view of the art known underlying lesions of atherosclerosis and known treatments of atherosclerosis as asknowledged in the Background of the Invention on pages 1-2 of the instant specification and in view of the art known modes of administration practiced by the ordinary artisan at the time the invention was made, as acknowledged on pages 12-16 of the instant specification; one of ordinary skill in the art would have been motivated to administer the anti-P-selectin antibodies, as taught by the primary references in various vessel-occlusive techniques given its properties of inhibiting platelet-leukocyte interactions for various clinical applications, including atherosclerosis and reperfusion injury with an expectation of success at the time the invention was made.

Given the art known practice of modes of administrations and dosing depending on a variety of factors and clinical symptoms known to the ordinary artisan at the time the invention was made, as taught by Palabrica et al. and Coller et al. In cardiovascular diseases, the claimed limitations were met or would have been obvious variants in meeting the needs of the patients in order to achieve a therapeutic effect depending on the symptom at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

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